UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 3 1993

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: CIDEX OPA---Company Response to Agency Assessment, Submitted Under MRID 422645-03
ID #007078-RT

Chemical: 623C (129017)
RD Record: S-415596
HED Projects: D176717

FROM: Irving Mauer, Ph.D., Geneticist
Toxicology Branch-I
Health Effects Division (H7509C)

TO: John Lee/V. Goncaro~~x~~s, PM 31
Antimicrobial Program Branch
Registration Division (H7505C)

THRU: Karl P. Baetcke, Ph.D., Chief
Toxicology Branch-I
Health Effects Division (H7509C)

Registrant: Johnson & Johnson Medical Inc. (JJMI)
Arlington, TX

Request: Review registrant's comments and submissions with respect to any outstanding (tox) data requirements, specifically the Agency's assessment of the following subchronic oral rat study:

> Subchronic Toxicity Study in Rats with O-Phthalaladehyde, performed by Hazelton Labs. America (HLA), unpublished Final Report No. HLA-256-116, dated August 31, 1989 (EPA MRID No. 412552-20).....

which was initially graded CORE-SUPPLEMENTARY, since the authors claimed they could not establish a NOEL (the LDT was 5 mg/kg/day), due to histopathological effects discernible at all doses.

Registrant's Submission:

JJMI has submitted point-for-point comments in rebuttal to the unsatisfactory regulatory assessment of the rat subchronic study.

In that submission, JJMI agrees with the Agency on the need for an additional study employing an appropriate dose schedule to resolve the equivocation about a NOEL. On the other hand, the registrant maintains that the data contained in the original study provides for establishing 5 mg/kg/day as an appropriate NOEL (with 25 mg/kg/day as the LOEL).

Agency Appraisal:

We agree with both the registrant and the contractor (Dynamac) on assigning the LDT (5 mg/kg/day) as the NOEL for regulatory purposes and thus this study can be upgraded to CORE-MINIMUM.

IM/ccm/Disk Mauer 526/chem 623C/1/14/93